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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Cook

Serial No.: 08/877,317 **Group Art Unit: 1633**

Filed: June 17, 1997 **Examiner: J. Martinell**

For: PNA-DNA-PNA CHIMERIC MACROMOLECULES

I, Gregory L. Hillyer, Registration No. 44,154 certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

On December 30, 1999

Gregory L. Hillyer, Registration No:44,154

Assistant Commissioner
for Patents
Washington, D.C. 20231

REQUEST FOR RECONSIDERATION

This responds to the Office Action mailed on September 27, 1999, in connection with the above-identified patent application.

Claims 13-16, 19, 20, and 24-26 are pending in this patent application.

All pending claims stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Applicants respectfully request reconsideration of this rejection, as it is now undisputed that those skilled in the art would be able to practice the claimed methods and obtain some measurable result. The Office Action presents no evidence or reasoning to the contrary, and although the Office Action identifies certain problems that allegedly would be encountered in

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practicing the claimed methods -- and criticizes Applicant's specification for allegedly not addressing these problems -- there is no requirement in the patent laws that patentable inventions be problem-free, or that a patent specification address all potential problems that might be encountered in practicing an invention. In fact, it is improper for the PTO to require any showing regarding the degree of effectiveness of therapeutic inventions, such as those now claimed M.P.E.P. § 2107.02; *In re Sichert,* 566 F.2d 1154 (C.C.P.A. 1977).

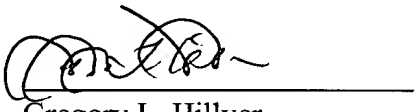
Not only does the mere existence of problems associated with the claimed inventions not negate their patentablility, but such problems are actually to be *expected.* It is well-established that pharmaceutical inventions usually require further research and development. *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995). Were such inventions not patentable long before being optimized or ready for human use, the incentive to fully research and develop vital drugs and potential cures would be completely removed. *Id.* at 1567-68.

Although the Office Action relies upon the Rojanasakul reference for its alleged disclosure of "problems," the reference nowhere so much as suggests that these "problems" are so significant as to prevent the claimed methods from producing measurable results. In fact, the reference specifically states that "there are numerous studies demonstrating the effectiveness of antisense ONs in various cells culture systems," and that "several ON drugs have already demonstrated enough promise to justify clinical trials" (Rojanasakul reference at page 118 and 126, respectively). To the extent that "problems" are identified in the Rojanasakul reference, such "problems" relate to

optimizing the performance of a therapeutic product, and not to simply obtaining measurable results. Since there is no requirement that an invention be optimized to be patentable, the disclosure of the Rojanasakul reference fails to support rejection of Applicant's claims.

Since there is no reasoning or evidence of record to suggest that those skilled in the art would not be able to practice the claimed invention to at least some measurable extent--and since such reasoning or evidence is required to support a rejection for lack of enablement--Applicants request that the rejection under §112, first paragraph, be reconsidered and withdrawn.

Respectfully submitted,



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Date: December 30, 1999

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